

531 Rec'd PCT/PT 26 OCT 2001

TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35.U.S.C. 371

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10/26/01

ATTORNEY'S DOCKET NO  
14177

U.S. APPLICATION NO  
**10/031859**

INTERNATIONAL APPLICATION NO.  
PCT/AU00/00397

INTERNATIONAL FILING DATE  
28 APRIL 2000

PRIORITY DATE CLAIMED  
28 APRIL 1999

TITLE OF INVENTION  
MODEL MEMBRANE SYSTEMS

APPLICANT(S) FOR DO/EO/US  
ALTIN, JOSEPH and PARISH, CHRISTOPHER RICHARD

Applicant herewith submits to the United States Designated /Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a FIRST submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(I).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19<sup>th</sup> month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ has been transmitted by the International Bureau.
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☒ have been transmitted by the International Bureau
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11. to 16. below concern other document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
  - ☐ A SECOND or SUBSEQUENT preliminary amendment.
14. ☐ A substitute specification.
15. ☐ A change of power of attorney and/or address letter.
16. ☒ Other items or information:
  - a. ☒ a copy of the International Search Report (PCT/ISA/210)
  - b. ☐ a copy of the International Preliminary Examination Report (PCT/IPEA/409)
  - c. ☒ cover page of PCT application No. PCT/AU00/00397 was published in English under publication number WO 00/64471 on 2 NOV 2000.

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INTERNATIONAL APPLICATION NO. PCT/AU00/00397		INTERNATIONAL FILING DATE 28 APRIL 2000		PRIORITY DATE CLAIMED 28 APRIL 1999	
17. [X] The following fees are submitted: <b>Basic National Fee (37 CFR 1.492(a)(1)-(5)):</b>  Neither international preliminary examination fee (37 CFR 1.482) Nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO (1.492(a)(3)) \$1,040.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO (1.492(a)(5)) \$890.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO (1.492(a)(2)) \$740.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) (1.492(a)(1)) \$710.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) \$100.00  <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b> \$1040.00				CALCULATIONS PTO USE ONLY	
Surcharge of \$130.00 for furnishing the oath or declaration later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 C.F.R. 1.492(e)).				\$0.00	
Claims	Number Filed	Number Extra	Rate	\$	
Total Claims	39 -20=	19	X \$ 18.00	\$342.00	
Independent Claims	7 -3=	4	X \$ 84.00	\$336.00	
Multiple dependent claim(s) (if applicable)			+ \$280.00	\$	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$1718.00	
Reduction by 1/2 for filing by small entity, if applicable				\$	
<b>SUBTOTAL =</b>				\$	
Processing fee of \$130.00 for furnishing the English translation later than [ ] 20 [ ] 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	\$
<b>TOTAL NATIONAL FEE =</b>				\$1718.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$ 0.00
<b>TOTAL FEES ENCLOSED =</b>				\$1718.00	
				<b>Amt. refunded</b>	\$
				<b>charged</b>	\$
a. [X] A check in the amount of \$1718.00 to cover the above fees is enclosed. b. [ ] Please charge our Deposit Account No. 04-1420 in amount of \$ to cover the above fees. A copy of this sheet is enclosed. c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 04-1420. A copy of this sheet is enclosed. <b>NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.</b> <b>SEND ALL CORRESPONDENCE TO:</b> Dorsey & Whitney LLP 250 Park Avenue New York, New York 10177					
				<i>Janet M. Maister</i> Signature October 26, 2001 Date Reg. No. 35,263 Registration No.	

Docket: 14177

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor:	Joseph Altin
Appln. No.:	TO BE ASSIGNED
Filed:	October 26, 2001
Title:	MODEL MEMBRANE SYSTEMS

PRELIMINARY AMENDMENT

BOX PCT  
Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination of the above-identified application, please enter the following amendment:

IN THE CLAIMS

Please amend claims 3, 7, 9-11, 13, 23, 24, 29, 33, 35 and 39 as follows:

3. (Amended) A method according to Claim 1 wherein some of the molecules of a biological and/or synthetic membrane or liposomes are modified by a covalent attachment of a metal chelating group, with metal chelating groups orientated toward the outside surface of said membranous structure.

7. (Amended) A method according to Claim 1 wherein the membranous structure is a suspension of micelles or liposomes formed from the amphiphilic molecules by sonication, or extrusion/filtration techniques.

9. (Amended) A method according to Claim 1 wherein a proportion of the amphiphilic molecules in the biological and/or synthetic membrane or liposomes have been modified by a covalent attachment of a metal chelating group.

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10. (Amended) A method according to Claim 1 wherein the amphiphilic molecules in the biological and/or synthetic membrane or liposomes are surfactant molecules having a hydrophilic head portion and one or more hydrophobic tails.

11. (Amended) A method according to Claim 1 wherein the polypeptide tag comprises a sequence of amino acid residues that can bind to the metal chelating groups attached to the said biological and/or synthetic membrane or liposomes.

13. (Amended) A method according to Claim 11 wherein the polypeptide tag comprises at least five amino acid residues.

23. (Amended) A method according to Claim 21 wherein the biological membrane is from a tumor cell.

24. (Amended) A method according to Claim 21 for use in enhancing or modifying immunity to tumors, for modifying any biological response, or for the treatment of any disease condition.

29. (Amended) A method according to Claim 27 wherein the molecule is a ligand, receptor, recombinant protein, polysaccharide, glycoprotein or antigen.

33. (Amended) A method according to Claim 31 wherein the anchored or engrafted molecule is a receptor, ligand, glycoprotein, polysaccharide or recombinant polypeptide.

35. (Amended) A method according to Claim 27 when used to enhance immunity to a specific tumor or disease.

39. (Amended) A vaccine according to Claim 37 prepared by the steps of:

- (i) incubating the liposomes, cells or membranous material with a chelator lipid such as NTA-DTDA, or a mixture of amphiphilic molecules containing a chelator lipid, to allow the lipid to incorporate in the cells or membranes;

- (ii) washing off any unincorporated lipid by centrifugation or filtration and resuspension of the liposomes, cells or membranous structures in the appropriate solution or buffer;
- (iii) incubating the liposomes, cells or membranous structures with incorporated chelator lipid with said molecules to be engrafted; and
- (iv) washing off unincorporated molecular material.

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Application Number:

Docket: 14177

REMARKS

The claims have been amended to remove multiple dependencies. No new matter has been added.

Favorable consideration of claims 1-39 is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Marked-up Version Showing Changes.**"

Respectfully submitted,

DORSEY & WHITNEY LLP

Date: October 26, 2001

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MARKED-UP VERSION SHOWING CHANGES

IN THE CLAIMS

3. (Amended) A method according to Claim 1 [or 2] wherein some of the molecules of a biological and/or synthetic membrane or liposomes are modified by a covalent attachment of a metal chelating group, with metal chelating groups orientated toward the outside surface of said membranous structure.

7. (Amended) A method according to Claim 1 [or 2 or 3 or 4 or 5 or 6] wherein the membranous structure is a suspension of micelles or liposomes formed from the amphiphilic molecules by sonication, or extrusion/filtration techniques.

9. (Amended) A method according to Claim 1 [or 2] wherein a proportion of the amphiphilic molecules in the biological and/or synthetic membrane or liposomes have been modified by a covalent attachment of a metal chelating group.

10. (Amended) A method according to Claim 1 [Claims 1 or 9] wherein the amphiphilic molecules in the biological and/or synthetic membrane or liposomes are surfactant molecules having a hydrophilic head portion and one or more hydrophobic tails.

11. (Amended) A method according to [any one of the preceding claims] Claim 1 wherein the polypeptide tag comprises a sequence of amino acid residues that can bind to the metal chelating groups attached to the said biological and/or synthetic membrane or liposomes.

13. (Amended) A method according to Claim 11 [or 12] wherein the polypeptide tag comprises at least five amino acid residues.

23. (Amended) A method according to Claim 21 [or 22] wherein the biological membrane is from a tumor cell.

24. (Amended) A method according to Claim 21 [or 22 or 23] for use in enhancing or modifying immunity to tumors, for modifying any biological response, or for the treatment of any disease condition.

29. (Amended) A method according to Claim 27[or 28] wherein the molecule is a ligand, receptor, recombinant protein, polysaccharide, glycoprotein or antigen.

33. (Amended) A method according to Claim 31 [or 32] wherein the anchored or engrafted molecule is a receptor, ligand, glycoprotein, polysaccharide or recombinant polypeptide.

35. (Amended) A method according to [any one of Claims 27 to 34] Claim 27 when used to enhance immunity to a specific tumor or disease.

39. (Amended) A vaccine according to Claim [36 or 38] 37 prepared by the steps of:

- (i) incubating the liposomes, cells or membranous material with a chelator lipid such as NTA-DTDA, or a mixture of amphiphilic [moleculescontaining] molecules containing a chelator lipid, to allow the lipid to incorporate in the cells or membranes;
- (ii) washing off any unincorporated lipid by centrifugation or filtration and resuspension of the liposomes, cells or membranous structures in the appropriate solution or buffer;
- (iii) incubating the liposomes, cells or membranous structures with incorporated chelator lipid with said molecules to be engrafted; and
- (iv) washing off unincorporated molecular material.